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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,290	03/20/2001	D. Wade Walke	LEX-0151-USA	1779

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EXAMINER

CHISM, BILLY D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/813,290

Applicant(s)

WALKE ET AL.

Examiner

Billy D Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This Office Action is in response to Paper Number 10, filed 19 September 2002, wherein Applicants elected Group I, Claims 1-4 drawn to a nucleic acid sequence of SEQ ID NO: 1. Claims 1-4 are currently pending in the application and claims 5-10 are canceled.

Objections

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The examiner objects to the use of the term "Novel." To obviate this objection, Applicants should consider deleting the term "Novel" from the title.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001

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Claim 1 is drawn to any contiguous 24 amino acids. There are no features or sequences defined that actually describe the claimed genus.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, i.e., any fragment containing 24 contiguous amino acids.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There is no single species of the claimed genus disclosed that is within the scope of the claimed genus. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the

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present claim encompasses numerous species that are not further described. There is substantial variability among the possible species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises any contiguous 24 amino acids. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Furthermore, Claim 2 is drawn to a nucleic acid which hybridizes to SEQ ID NO:1. Because the claim does not state fully complementary or over the entire length, it encompasses partial sequences, which once again are not described and lack written description.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected for the indefinite recitation of "sequence first disclosed in SEQ ID NO: 1. As stated in the claim, it is not clear if the Applicants mean the entire sequence set forth in SEQ ID NO:1, some portion of the sequence or an earlier version.

Regarding claim 2, "stringent conditions" is understood to mean the conditions as disclosed and referred to on page 5, lines 1-25 and page 6 lines 1-11.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

7. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification discloses using the NHP oligonucleotides as hybridization probes (page 6, line 12) however, this can be performed by many oligonucleotides known in the art. At page 7, lines 1-10 disclose using the sequence for identifying and characterizing temporal and tissue specific expression of a gene, however, there is no specific gene disclosed for which the claimed sequence could be used that could not be performed by any known oligonucleotides in the art.

The conclusion is found for the micro array-based analysis disclosed on page 7, lines 27-36. The use of the claimed sequence as a probe (page 8, lines 1-9) for drug discovery offers no specific types or classes of drugs for testing that could not be tested with any known oligonucleotides.

The use of the claimed sequence to screen collections of genetic material from patients with particular medical conditions does not specify any particular medical condition that could not be screened for by any known oligonucleotides. Again, the specification on page 11 lines 3-17, discloses the use of the claimed sequence for screening a human genomic library, however, there is no disclosure that this use cannot be performed by many known oligonucleotides in the art.

The use of the claimed sequence for construction of a cDNA library (page 11-13) for detection of mutant NHPs or other purposes does not offer a specific utility since it is not disclosed what the utility of the claimed non-mutated sequence is. Furthermore, there is no specifically disclosed utility to the proteins to the claimed oligonucleotide. The specification discloses the use of the

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protein encoded by the claimed oligonucleotide (pages 16-17) for production of antibodies, reagents in assays, identification of NHP related gene products, and for screening assays for pharmaceutical reagents, however, there is no specifically disclosed use for the antibodies beyond use with the protein product of the claimed oligonucleotide. Furthermore, there are no specifically disclosed mental, biological, or medical disorders and diseases for which the proteins could be used to screen for pharmaceutical reagents. For the reasons listed above, the claimed invention lacks patentable utility.

Claims 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation. The factors include:

- 1) the nature of the invention and breadth of the claims;

The claimed invention is drawn to a nucleic acid molecule comprising SEQ ID NO: 1. There are no disclosed utilities for the claimed invention that would lend to an assessment of the nature of the invention.

- 2) the predictability or unpredictability of the art;

There is no claimed usage in the claims and thus no comparable predictability or unpredictability to the art.

- 3) the amount of direction or guidance presented;

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The specification provides no direction regarding the use of the invention. Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). Without a claimed usage for the claimed invention or intended usage there is no available comparison to be made to the art regarding direction or guidance. Thus, for there to be use of the claimed invention, it would require disclosure of some usage or patentable application for the claimed invention.

4) the presence or absence of working examples;

The specification is without adequate disclosure of working examples and a claimed or disclosed use for the claimed invention.

5) the quantity of experimentation necessary;

As there is no disclosed patentably distinct utility for the claimed invention, it would require a undue quantities of experimentation for a use of the claimed invention.

6) the state of the prior art and relative skill of those skilled in the art; and,

There can be no comparison with the prior art as there is no comparable disclosed utility of the claimed invention.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism
16 October 2002


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600